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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/550,107 04/14/00 VERWAERDE P B0192/7013(E)

ELIZABETH R PLUMMER
C/O WOLF GREENFIELD AND SACKS P C
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON MA 02210-2211

HM22/0928

EXAMINER

WHITEMAN, B

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/550,107

Applicant(s)

VERWAERDE ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-186 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-186 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Claims 1-186 are pending and under consideration in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 8-45, 51-99, 101, 105-126, 164, 165, and 179-186, drawn to a method of identifying chemical substances, which, have potential pharmacological activity using nematode worms, which method comprises **detecting a signal, indicating phenotype, physiological, behavioral, or biochemical changes** in the nematode using non-visual detection means, classifiable in class 800, subclass 3, class 424, subclass 9.6, subclass 93.7.
- II. Claims 3-4, 46, 47, 100, 140, 141, 166, and 167, drawn to a method of identifying further components of the biochemical pathway on which a compound having a defined effect on how a nematode worm acts, classifiable in class 424, subclass 9.6, subclass 93.7.
- III. Claims 5-6, 48-49, 102, 103, 168, and 169 drawn to a method of identifying chemical substances which **suppresses** the effect of a first compound, which compound has a defined effect on nematode worms, which comprise **detecting a signal indicating phenotypic, physiological, behavioural, or biochemical changes** in the nematode worms using non-visual detection means, classifiable in class 424, subclass 9.6, subclass 93.7.
- IV. Claims ^{5, 48, 102}_{7, 50, 104} and ¹⁶⁸₁₇₀₋₁₇₈, drawn to a method of identifying chemical substances which **enhances** the effect of a first compound, which compound has a defined effect on nematode worms, which comprise **detecting a signal indicating phenotypic, physiological, behavioral, or biochemical changes** in the nematode worms using non-visual detection means, classifiable in class 435, subclass 4.

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V. Claims 127, 128, 132-139, and 145-163, drawn to a method of identifying chemical substances, which have potential pharmacological activity using nematode worms, which method comprises **detecting the amount of eggs or offspring produced** using non-visual detection means, classifiable in class 424, subclass 9.6, subclass 93.7.

VI. Claims 129, 130, 142, and 143, drawn to a method of identifying chemical substances which **suppresses** the effect of a first compound, which compound has a defined effect on nematode worms, which comprise **detecting the amount of eggs or offspring** produced using non-visual detection means, classifiable in class 424, subclass 9.6, subclass 93.7.

VII. Claims ^(a)131 and ^(b)144, drawn to a method of identifying chemical substances which **enhances** the effect of a first compound, which compound has a defined effect on nematode worms, which comprise **detecting the amount of eggs or offspring** produced using non-visual detection means, classifiable in class 424, subclass 9.6, subclass 93.7.

Claims 5, 48, 102, and 168 link(s) inventions III and IV. Claims 129 and 142 link(s) inventions VI and VII. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claims 5, 48, 102, 129, 142, 168. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a

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restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions I-VII constitutes patentably distinct inventions for the following reasons: Each of the inventions is directed to different goals and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above. For example, invention I is directed to different goals and materially distinct steps than invention III and IV. Furthermore, the search of invention I does not overlap with invention III and IV. In addition, groups I-IV are directed to different goals and materially distinct steps than groups V-VII (***e.g. the method steps of invention I-IV comprise detecting a signal, indication phenotype, physiological, behavioral, biochemical and the method steps of Inventions V-VII comprise detecting the amount of eggs or offspring produced***). The scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Furthermore, the method of I is not encompassed by II-VII. In addition, each invention is a patentably distinct method of using worms as discussed above in each group. Each of the inventions I-VII comprises materially distinct steps, and/or generates different functions and effects, and thus, is not required for use with one another.

If applicants elect group I, II, III, or IV; the applicant is further required to elect a species because claims 1, 2, 3, 5, 7 are generic to a plurality of disclosed patentably distinct species comprising: phenotypic, physiological, behavioral, or biochemical changes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

It appears, unless evidence to the contrary, that pharynx-pumping rate is a biochemical change. Thus, if applicants elect biochemical as the distinct species, then claims directed to biochemical changes in the respective group will also be examined. For example, if applicants elect group I and biochemical as the distinct species, then claims 44 and 45 will also be examined. However, if applicants elect group I and phenotypic, physiological, or behavioral as the distinct species, then claims 44, 45 and claims dependent therefrom will not be examined.

Furthermore, if applicants elect group I, the applicant is further required to elect a species because claims 28, 75, 96, 111 are generic to a plurality of disclosed patentably distinct species comprising: eggs, L1 stage, L2 stage, L3 stage, L4 stage, adult worms, or dauer worms. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicants elect group I, the applicant is further required to elect a species because claims 1, 30, 44, 62, 98, and 113 are generic to a plurality of disclosed patentably distinct species comprising: transgenic, humanized, wild type, or mutant. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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If applicants elect group I, the applicant is further required to elect a species because claims 32, 69, 115 are generic to a plurality of disclosed patentably distinct species comprising a toxic gene selected from ataxin, alpha-synuclein, ubiquitin, the tau gene, the Huntington's gene product, the best macular dystrophy gene product, the age-related macular dystrophy product, or the unc-53 gene product. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicants elect group I, the applicant is further required to elect a species because claim 68 is generic to a plurality of disclosed patentably distinct species comprising: a C. Elegan carrying a mutant gene encoding SERCA protein; PLB protein; SLN protein; SERCA and PLB protein; SERCA and SLN protein; PLB and SLN protein; or SERCA, PLB, SLN proteins. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicants elect group IV, the applicant is further required to elect a species because claim 176 is generic to a plurality of disclosed patentably distinct species comprising a toxic gene selected from ataxin, alpha-synuclein, ubiquitin, the tau gene, the Huntington's gene product, the best macular dystrophy gene product, the age-related macular dystrophy product, or the unc-53 gene product. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicants elect group V, the applicant is further required to elect a species because claims 134 and 145 are generic to a plurality of disclosed patentably distinct species comprising mutant, transgenic, or humanized C. Elegans. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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If applicants elect group V, the applicant is further required to elect a species because claim 151 is generic to a plurality of disclosed patentably distinct species comprising a specific antibody which binds to eggs, L1, L2, L3, or L4 stage nematodes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicants elect group V, the applicant is further required to elect a species because claims 135 and 146 are generic to a plurality of disclosed patentably distinct species comprising a toxic gene selected from ataxin, alpha-synuclein, ubiquitin, the tau gene, the Huntington's gene product, the best macular dystrophy gene product, the age-related macular dystrophy product, or the unc-53 gene product. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the literature search required for Group I is not required for Group II-VII, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775.


The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-8724.

Brian Whiteman, 1633
9/27/01


DAVE T. NGUYEN
PRIMARY EXAMINER